:: 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Additional Comment Period for Updated HRSA-supported Women's Preventive Services

Guidelines Statement on Breastfeeding Services and Supplies

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and

Human Services.

ACTION: Notice.

SUMMARY: On August 20, 2021, HRSA published a notice soliciting public comments

regarding proposed updated draft recommendations to the HRSA-Supported Women's

Preventive Services Guidelines (Guidelines) in the areas of Well-Women Preventive Visits,

Counseling for Sexually Transmitted Infections, and Breastfeeding Services and Supplies,

which, when accepted by HRSA, are required to be covered without cost-sharing by certain

health insurance issuers under the Public Health Service Act. The updated draft recommendation

statements were developed through a national cooperative agreement, the Women's Preventive

Services Initiative (WPSI), by the American College of Obstetricians and Gynecologists

(ACOG). Since the publication of that notice, WPSI has further updated its recommendation

statement on Breastfeeding Services and Supplies. HRSA encourages members of the public to

review this revised updated recommendation statement and provide comments for consideration.

DATES: Members of the public are invited to provide written comments no later than

INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL

REGISTER]. All comments received on or before this date will be reviewed and considered by the WPSI Multidisciplinary Steering Committee.

ADDRESSES: Members of the public interested in providing comments on the draft recommendation statements can do so by accessing the initiative's webpage at https://www.womenspreventivehealth.org/.

FOR FURTHER INFORMATION CONTACT: Kimberly Sherman, HRSA, Maternal and Child Health Bureau, telephone (301) 443-8283, email: wellwomancare@hrsa.gov.

SUPPLEMENTARY INFORMATION: HRSA established the Guidelines in 2011 based on a study and recommendations by the Institute of Medicine, now known as the National Academy of Medicine, developed under a contract with the Department of Health and Human Services. Under section 1001(5) of the Patient Protection and Affordable Care Act, P.L. 111-148, which added section 2713 to the Public Health Service Act, 42 U.S.C. 300gg-13, the preventive care and screenings set forth in the Guidelines are required to be covered without cost-sharing by certain health insurance issuers. Since 2011, there have been advancements in science and gaps identified in these guidelines, including a greater emphasis on practice-based clinical considerations. Accordingly, since March 2016, HRSA has supported cooperative agreements with ACOG to convene a coalition representing clinicians, academics, and consumer-focused health professional organizations to conduct a rigorous review of current scientific evidence and make recommendations to HRSA regarding updates to the Guidelines to improve adult women's health across the lifespan. HRSA then decides whether to support, in whole or in part, the recommended updates to the Guidelines. Under the cooperative agreement, ACOG formed WPSI, consisting of an Advisory Panel and two expert committees, the Multidisciplinary Steering Committee (MSC) and the Dissemination and Implementation Steering Committee (DISC), which are comprised of a broad coalition of organizational representatives who are experts in disease prevention and women's health issues. Through oversight by the Advisory Panel, MSC supports the development and implementation of the Guidelines through the review

of existing evidence and recommendation development. Specifically, the MSC examines the evidence to develop new and update existing recommendations for women's preventive services. DISC takes the HRSA-approved recommendations, developed by the MSC, and works to disseminate them through the development of implementation tools and resources for both patients and practitioners.

In March 2021, ACOG engaged in a process to consider and review new information and evidence to determine whether to recommend updates to the Guidelines. ACOG bases its recommended updates to the Guidelines on review and synthesis of existing clinical guidelines and new scientific evidence, following the National Academy of Medicine standards for establishing foundations for and rating strengths of recommendations, articulation of recommendations, as well as external reviews. Additionally, ACOG incorporates processes to assure opportunity for public comment, including participation by patients and consumers, in the development of the updated Guideline recommendations.

This notice solicits comments from the public on a revised draft recommendation statement on Breastfeeding Supplies and Services. The updated draft recommendation statement that was published on August 20, 2021 and the revised recommendation statement that HRSA recently received from ACOG are provided below. WPSI will consider and, as necessary, incorporate additional public comment in its recommendation statement. HRSA will then decide whether to support, in whole or in part, the recommended updates to the Guidelines.

Clinical Recommendation Statement as Published on August 20, 2021

The MSC updated clinical recommendation included consultative services to optimize successful initiation and maintenance of breastfeeding: "The WPSI recommends comprehensive lactation support services (including consultation, counseling, education, and breastfeeding equipment and supplies) during the antenatal, perinatal, and postpartum periods to optimize the successful initiation and maintenance of breastfeeding."

Revised Clinical Recommendation Statement

The MSC has made two further updates to the clinical recommendation statement for

breastfeeding. The first addresses provider type in the provision of breastfeeding services to

reflect that breastfeeding education can be provided by clinicians and through peer support

services. The second update moves a paragraph on breastfeeding equipment and supplies

from the implementation section of the guideline into the clinical recommendation

component, making it a substantive addition to the Guidelines with corresponding effect

under Section 2713. As revised, the clinical recommendation statement provides:

"The WPSI recommends comprehensive lactation support services (including consultation;

counseling; education by clinicians and peer support services; and breastfeeding equipment

and supplies) during the antenatal, perinatal, and postpartum periods to optimize the

successful initiation and maintenance of breastfeeding. Breastfeeding equipment and

supplies include, but are not limited to, double electric breast pumps (including pump parts

and maintenance) and breast milk storage supplies. Access to double electric pumps should

be a priority to optimize breastfeeding and should not be predicated on prior failure of a

manual pump. Breastfeeding equipment may also include equipment and supplies as

clinically indicated to support dyads with breastfeeding difficulties and those who need

additional services."

Members of the public can view the complete revised updated draft recommendation

statement by accessing the initiative's webpage at

https://www.womenspreventivehealth.org/.

Diana Espinosa,

Acting Administrator.

[FR Doc. 2021-26700 Filed: 12/9/2021 8:45 am; Publication Date: 12/10/2021]